

U.S. Patent Application Serial No. 09/731,863  
Amendment dated October 31, 2003  
Reply to OA of **June 3, 2003**

### **REMARKS**

Claims 20-48 are pending in this application. Amendments to claims 23, 24, 35 and 36 are proposed herein.

In the amendments to claims 23, 24, 35 and 36, the recitation of "phenylalanine" has been deleted ("phenylalanine" was misspelled in claim 23). Applicants submit that no new matter is added by these amendments.

**Claims 20-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. (U.S. Patent No. 4,971,698) in view of Yamada et al. (U.S. Patent No. 4,945,443) and Soon-Shiong et al. (U.S. Patent No. 5,700,848).**

The rejection of claims 20-48 is respectfully traversed and reconsideration of the rejection is respectfully requested.

First of all, in the rejection, the Examiner states that:

"Weber et al. discloses a method and product for treating environmental pollutants which includes immobilization of a microorganism in a gel-type organic polymer which is contacted with the environmental pollutant. The above claims differ by specifying that the microorganisms are incorporated with a polymer containing a sugar component in which fructofuranosyl group(s) is/are bonded to a fructosyl group at the  $\beta$ -2,6 position or a polyamino acid."

The Examiner cites Yamada et al. as disclosing that it is known in the art to immobilize microorganisms within xantham gum which is a microorganism-produced polymer, noting that xantham gum differs from the particular polysaccharides recited in claim 20. The Examiner cites

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Soon-Shiong et al. as disclosing that a list of known polymers, and that “the list discloses that levan and polyamino acids are equivalents to the xantham gum of Yamada et al. and alginate, carrageenan and chitosan of Weber et al. (See column 6, lines 51 to column 7, line 6).”

Applicants respectfully disagree that these polymers are “equivalents” or that Soon-Shiong et al. states that these are equivalents. Rather, these lines of the reference state: “Examples of biocompatible materials include polysaccharides such as alginate, .....,” and proceed to list at least 50 different materials and classes of materials. The reference does **not** state that these materials are **equivalent**, and clearly these different biological materials are **not** considered art-recognized equivalents.

Moreover, Soon-Shiong et al.’s list of examples is in the context of biocompatible materials which are modified to be capable of undergoing free radical polymerization. The immobilization in Weber et al. does not use Soon-Shiong’s process, and there appears to be no suggestion in either reference to substitute any of Soon-Shiong’s long list of biocompatible materials for the materials such as carrageenan in Weber et al.’s invention.

To further demonstrate the non-equivalence of the compounds in Soon-Shiong’s list, Applicants here present an additional Declaration under 37 CFR 1.132 by Akihito Tsuchiya, providing additional experimental data demonstrating the unexpected results of the present invention.

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In particular, in the experiment presented in the present Declaration under 37 CFR 1.132, synthetic sewage containing 4-octylphenol was treated in nine treatments with microbial treatment agents commensurate with the present invention, as summarized in Table Z on page 6. These treatment agents are prepared using the specific microorganism-produced polymer (levan produced by *Bacillus*, *Acetobacter* or *Pseudomonas*;  $\beta$ -2,6 fructan; and various polyamino acids) can degrade the 4-octylphenol. In contrast, the Declaration demonstrates that microbial treatment agents prepared using alginic acid, carrageenan or chitosan cannot degrade 4-octylphenol.

As evidenced by the different results, the inventive microbial treatment agents are **not equivalent** to those using alginic acid, carrageenan or chitosan, and the biocompatible materials listed by Soon-Shiong are clearly **not equivalent to each other**.

Moreover, it is apparent that the difference in the treatment effect shown in Table Z is **completely unexpected** based on any of the cited references. Even if there were a suggestion to combine the references to produce the recitation of claim 20, 21, 33 or 34, these data demonstrate that the particular limitations of these claims yield unexpected results over the prior art.

Applicants submit that the unexpected results presented in the Declaration are fully commensurate with the present claims. In particular, the examples of *Bacillus*, *Acetobacter* or *Pseudomonas* bacteria-produced polysaccharide in the enclosed Declaration are commensurate with claim limitations regarding polymer II. The example of  $\beta$ -2,6 fructan in the enclosed Declaration is commensurate with claim limitation regarding polymer III. The examples of poly-leucine, poly-

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alanine, poly-arginine, poly-lysine hydrobromide and poly-benzyl-L-aspartate in the enclosed Declaration are commensurate with claim limitations regarding polymer IV, especially with limitations of claims 23, 24, 35 and 36.

In the final Office action, in the Response to arguments, the Examiner indicated that the Declaration under 37 CFR 1.132 filed on March 17, 2003, was not commensurate in scope with the claimed invention. Applicants respectfully disagree, noting the following points:

The example of *Zoogloea* bacteria-procured polysaccharide in the Declaration filed March 17, 2003, is commensurate with claim limitation regarding polymer I. The example of poly-L-glutamic acid- $\gamma$ -benzyl ester in the Declaration filed March 17, 2003, are commensurate with claim limitations regarding polymer IV, especially with limitations of claims 23, 24, 35 and 36.

The Declaration of March 17, 2003, taken with the current Declaration, clearly demonstrate unexpected results commensurate in scope with the claims. The excellent effects of the present invention cannot be achieved by using other gel-type organic polymers such as alginic acid, carrageenan and chitosan disclosed in Weber et al. The effects are completely unexpected over the references.

In addition to the above arguments, Applicants note that the following advantages of the present invention are not suggested by the cited references:

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(i) The microorganisms retain high growth rates even in the presence of a high concentration of a pollutant, and exhibit their biological activities necessary for assimilation or degradation of the pollutant (see the specification, page 4, lines 13-20, and page 21, lines 10-17).

(ii) The pollutant can be concentrated efficiently (see the specification, page 4, lines 20-23, and page 21, lines 17-22).

Owing to advantages (i) and (ii), the present invention achieves the excellent effect that the pollutant can be efficiently assimilated or degraded (specification, page 4, line 24, to page 4, line 6, and page 21, lines 10-22).

Examples 3 and 4 in the specification demonstrate this excellent effect.

This excellent effect is achieved by using the specific microorganism-produced polymers described below I) to IV).

- I) a cohesive or adhesive polysaccharide produced from bacteria of the genus *Zoogloea*;
- II) a levan produced from bacteria of the genus *Bacillus*, *Acetobacter*, or *Pseudomonsa*;
- III) a polymer containing a sugar component in which fructofuranosyl group(s) is/are bonded to a fructosyl group at the  $\beta$ -2,6 position; and
- IV) a poly amino acid.

As noted above, these effects are demonstrated by the Declarations under 37 CFR 1.132.

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To summarize, Applicants note that Yamada et al. simply discloses an easy and economic technique for immobilizing microorganisms in a xanthan gum or its derivatives, and nowhere teaches the specific microorganism-produced polymers for use in the present invention.

Weber et al. also discloses nothing about the specific microorganism-produced polymers used in the present invention.

Soon-Shiong et al. merely discloses a list of biocompatible polymers (col. 6, line 51 to col. 7, line 6), and does not teach polymers usable in a microbial treatment agent for treating an environmental pollutant.

Applicants therefore submit that a *prima facie* case of obviousness cannot be made using these three references and, further, that Yamada et al., Weber et al. and Soon-Shiong et al. do not teach or suggest the excellent effect accomplished by the present invention. Applicants submit that claims 20-48 are novel and non-obvious over Weber et al. (U.S. Patent No. 4,971,698), Yamada et al. (U.S. Patent No. 4,945,443) and Soon-Shiong et al. (U.S. Patent No. 5,700,848), taken separately or in combination.

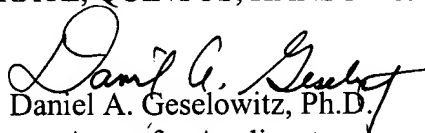
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If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact Applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, Applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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Enclosures: Declaration under 37 C.F.R. 1.132 executed October 17, 2003

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